

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of	)	
	)	
Prem S. PAUL et al.	)	Group Art Unit: Not Yet Assigned
	)	
Application No.: Not Yet Assigned	)	Examiner: Not Yet Assigned
(Divisional of 08/301,435	)	
filed September 1, 1994)	)	Confirmation No.: Not Yet Assigned
	)	
Filed: Concurrently herewith	)	
	)	
For: POLYNUCLEIC ACIDS ISOLATED	)	
FROM A PORCINE	)	
REPRODUCTIVE AND	)	
RESPIRATORY SYNDROME VIRUS	)	
(PRRSV) AND PROTEINS	)	
ENCODED BY THE	)	
POLYNUCLEIC ACIDS	)	

**PRELIMINARY AMENDMENT**

Commissioner for Patents  
PO Box 1450  
Alexandria, Virginia 22313-1450

Sir:

Prior to examination of the above-identified application, please amend the  
application as follows.

**AMENDMENTS TO THE SPECIFICATION:**

Please replace the paragraph beginning on page 1, line 7 and ending on line 12 with the following amended paragraph:

This application is a divisional of Application Serial No. 08/301,435, filed September 1, 1994, now pending, which ~~This is a~~ is a continuation-in-part of application Serial No. 08/131,625, filed on October 5, 1993, pending now U.S. Patent 5,695,766, which is a continuation-in-part of application Serial No. 07/969,071, filed on October 30, 1992, now abandoned. The entire contents of application Serial No. 08/131,625, filed on October 5, 1993, are incorporated herein by reference.

**AMENDMENTS TO THE CLAIMS:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**LISTING OF CLAIMS:**

1. (Presently amended) A purified preparation containing a polynucleotide encoding at least one polypeptide encoded by one or more open reading frames (ORF's) of ORFs 1-7 of a porcine reproductive and respiratory syndrome virus (PRRSV) wherein said polynucleotide has a sequence selected from the group consisting of the formulas (I), (II) and (III):

5'- $\alpha$ - $\beta$ - $\gamma$ -3' (I)

5'- $\gamma$ - $\delta$ - $\epsilon$ -3' (II)

5'- $\alpha$ - $\beta$ - $\gamma$ - $\delta$ - $\epsilon$ -3' (III)

wherein:

$\alpha$  encodes at least one polypeptide encoded by a polynucleotide selected from the group consisting of ORF 1a and 1b, ORF 2 and ORF 3 of the PRRSV;

$\beta$  is either a covalent bond or a linking polynucleic acid which does not cause a decrease in the severity of gross and microscopic pneumonia lesions caused by the PRRSV;

$\gamma$  is at least one copy of an ORF 5 from the PRRSV;

$\delta$  is a covalent bond or a linking polynucleic acid which does not materially affect transcription and/or translation of said polynucleic acid; and

$\epsilon$  encodes at least one polypeptide encoded by a polynucleotide selected from the group consisting of ORF 6 and ORF 7 of the PRRSV;

and when  $\delta$  is a covalent bond,  $\gamma$  may have a 3'-end which excludes the region overlapping with the 5'-end of a corresponding ORF 6.

2. (Canceled)

3. (Presently amended) A purified preparation containing a polynucleotide encoding at least one polypeptide encoded by one or more open reading frames (ORF's) of ORFs 1-7 of a porcine reproductive and respiratory syndrome virus (PRRSV) wherein the virus is characterized as highly virulent as determined by its ability to induce lesions in at least 51.9% of lung tissue 10 days post-inoculation of five-week-old colostrum-deprived, caesarean-derived pigs with  $10^5$  TCID<sub>50</sub> of said virus, and wherein said polynucleotide comprises multiple copies of ORF 5.

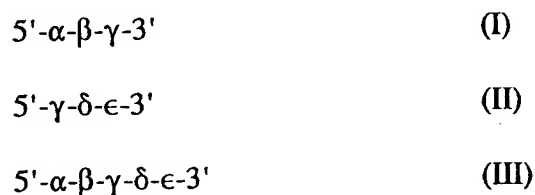
4.-5. (Canceled)

6. (Presently amended) The purified preparation of Claim 1, wherein said polynucleotide comprises ORF 2, ORF 3, ORF 5, ORF 6 or ORF 7 of any one of VR 2385, VR 2386, VR 2429, VR 2484 or VR 2475, or combinations thereof.

7. (Presently amended) The purified preparation of Claim 1, wherein said polypeptide is encoded by at least one of ORF's 2, 3, 5, and 6 of the viruses VR 2385, VR 2386, VR 2429, VR 2484 or VR 2475.

Claims 8-38 (Canceled)

39. (New) A purified preparation containing a polynucleotide encoding at least one polypeptide encoded by one or more open reading frames (ORF's) of the viruses ISU-51 (VR 2428), ISU-55 (VR 2430), ISU-3927 (VR 2431) or ISU-1894 (VR 2475), wherein said polynucleotide has a sequence selected from the group consisting of the formulas (I), (II) and (III):



wherein:

$\alpha$  encodes at least one polypeptide encoded by a polynucleotide selected from the group consisting of ORF 1a and 1b, ORF 2 and ORF 3 of the PRRSV;

$\beta$  is either a covalent bond or a linking polynucleic acid which does not cause a decrease in the severity of gross and microscopic pneumonia lesions caused by the PRRSV;

$\gamma$  is at least one copy of an ORF 5 from the PRRSV;

$\delta$  is either a covalent bond or a linking polynucleic acid which does not materially affect transcription and/or translation of said polynucleic acid; and

$\epsilon$  encodes at least one polypeptide encoded by a polynucleotide selected from the group consisting of ORF 6 and ORF 7 of the PRRSV;

and when  $\delta$  is a covalent bond,  $\gamma$  may have a 3'-end which excludes the region overlapping with the 5'-end of a corresponding ORF 6.

40. (New) A purified preparation containing a polynucleotide encoding at least one polypeptide encoded by one or more open reading frames (ORF's) of the viruses ISU-51 (VR 2428), ISU-55 (VR 2430), ISU-3927 (VR 2431) or ISU-1894 (VR 2475), wherein said ORF 5 is from a PRRSV comprising multiple copies of ORF 5.

41. (New) The purified preparation of Claim 39, wherein said polynucleotide comprises ORF 2, ORF 3, ORF 5, ORF 6 or ORF 7 of any one of VR 2428, VR 2430, VR 2431, or VR 2475, or ORF combinations thereof.

42. (New) The purified preparation of Claim 39, wherein said polypeptide is encoded by at least one of ORF's 2, 3, 5, and 6 of VR 2428, VR 2430, VR 2431, or VR 2475.

43. (New) A purified preparation of Claim 1 or Claim 39, containing one or more polynucleotide at least

(a) 98% identical to ORF 6 of the virus, or

(b) 98% identical to ORF 7 of the virus;

wherein the identity is determined using the following parameters:

- (i) a cost to open a gap 5;
- (ii) a cost to lengthen a gap of 25;
- (iii) a minimum diagonal length of 4; and
- (iv) a maximum diagonal offset of 10.

44. (New) The purified preparation of Claim 43, wherein said polynucleotide has a sequence selected from the group consisting of the formulas (I), (II) and (III):

5'- $\alpha$ - $\beta$ - $\gamma$ -3' (I)

5'- $\gamma$ - $\delta$ - $\epsilon$ -3' (II)

5'- $\alpha$ - $\beta$ - $\gamma$ - $\delta$ - $\epsilon$ -3' (III)

wherein:

$\alpha$  encodes at least one polypeptide encoded by a polynucleotide selected from the group consisting of ORF 1a and 1b, ORF 2 and ORF 3 of the viruses of Claim 43;

$\beta$  is either a covalent bond or a linking polynucleic acid which does not cause a decrease in the severity of gross and microscopic pneumonia lesions caused by the PRRSV of Claim 43;

$\gamma$  is at least one copy of an ORF 5 from the PRRSV of Claim 43;

$\delta$  is either a covalent bond or a linking polynucleic acid which does not materially affect transcription and/or translation of said polynucleic acid; and

$\epsilon$  encodes at least one polypeptide encoded by a polynucleotide selected from the group consisting of ORF 6 and ORF 7 of the PRRSV of Claim 43;

and when  $\delta$  is a covalent bond,  $\gamma$  may have a 3'-end which excludes the region overlapping with the 5'-end of a corresponding ORF 6.

45. (New) The purified preparation of Claim 44, wherein said ORF 5 is comprised of multiple copies of ORF 5.

46. (New) The purified preparation of Claim 3, wherein said polynucleotide comprises ORF 2, ORF 3, ORF 5, ORF 6 or ORF 7 of any one of VR 2385, VR 2386, VR 2429, VR 2484 or VR 2475, or combinations thereof.

47. (New) The purified preparation of Claim 3, wherein said polypeptide is encoded by at least one of ORF's 2, 3, 5, and 6 of the viruses VR 2385, VR 2386, VR 2429, VR 2484 or VR 2475.

48. (New) The purified preparation of Claim 3, containing one or more polynucleotide at least

- (a) 98% identical to ORF 6 of the virus, or
- (b) 98% identical to ORF 7 of the virus;

wherein the identity is determined using the following parameters:

- (i) a cost to open a gap 5;
- (ii) a cost to lengthen a gap of 25;
- (iii) a minimum diagonal length of 4; and



(iv) a maximum diagonal offset of 10.

49. (New) The purified preparation of Claim 48, wherein said polynucleotide has a sequence selected from the group consisting of the formulas (I), (II) and (III):

5'- $\alpha$ - $\beta$ - $\gamma$ -3' (I)

5'- $\gamma$ - $\delta$ - $\epsilon$ -3' (II)

5'- $\alpha$ - $\beta$ - $\gamma$ - $\delta$ - $\epsilon$ -3' (III)

wherein:

$\alpha$  encodes at least one polypeptide encoded by a polynucleotide selected from the group consisting of ORF 1a and 1b, ORF 2 and ORF 3 of the viruses of Claim 48;

$\beta$  is either a covalent bond or a linking polynucleic acid which does not cause a decrease in the severity of gross and microscopic pneumonia lesions caused by the PRRSV of Claim 48;

$\gamma$  is at least one copy of an ORF 5 from the PRRSV of Claim 48;

$\delta$  is either a covalent bond or a linking polynucleic acid which does not materially affect transcription and/or translation of said polynucleic acid; and

$\epsilon$  encodes at least one polypeptide encoded by a polynucleotide selected from the group consisting of ORF 6 and ORF 7 of the PRRSV of Claim 48;

and when  $\delta$  is a covalent bond,  $\gamma$  may have a 3'-end which excludes the region overlapping with the 5'-end of a corresponding ORF 6.

50. (New) The purified preparation of Claim 40, wherein said polynucleotide comprises ORF 2, ORF 3, ORF 5, ORF 6 or ORF 7 of any one of VR 2385, VR 2386, VR 2429, VR 2484 or VR 2475, or combinations thereof.

51. (New) The purified preparation of Claim 40, wherein said polypeptide is encoded by at least one of ORF's 2, 3, 5, and 6 of the viruses VR 2385, VR 2386, VR 2429, VR 2484 or VR 2475.

52. (New) A purified preparation of Claim 40, containing one or more polynucleotide at least

- (a) 98% identical to ORF 6 of the virus, or
- (b) 98% identical to ORF 7 of the virus;

wherein the identity is determined using the following parameters:

- (i) a cost to open a gap 5;
- (ii) a cost to lengthen a gap of 25;
- (iii) a minimum diagonal length of 4; and
- (iv) a maximum diagonal offset of 10.

53. (New) The purified preparation of Claim 52, wherein said polynucleotide has a sequence selected from the group consisting of the formulas (I), (II) and (III):



5'- $\alpha$ - $\beta$ - $\gamma$ - $\delta$ - $\epsilon$ -3'

(III)

wherein:

$\alpha$  encodes at least one polypeptide encoded by a polynucleotide selected from the group consisting of ORF 1a and 1b, ORF 2 and ORF 3 of the viruses of Claim 52;

$\beta$  is either a covalent bond or a linking polynucleic acid which does not cause a decrease in the severity of gross and microscopic pneumonia lesions caused by the PRRSV of Claim 52;

$\gamma$  is at least one copy of an ORF 5 from the PRRSV of Claim 52;

$\delta$  is either a covalent bond or a linking polynucleic acid which does not materially affect transcription and/or translation of said polynucleic acid; and

$\epsilon$  encodes at least one polypeptide encoded by a polynucleotide selected from the group consisting of ORF 6 and ORF 7 of the PRRSV of Claim 52;

and when  $\delta$  is a covalent bond,  $\gamma$  may have a 3'-end which excludes the region overlapping with the 5'-end of a corresponding ORF 6.

**REMARKS**

The above amendments have been made to improve the form of the specification. Claims 2, 4-5, and 8-38 have been canceled and Claims 1, 3, 6, and 7 are identical to claims which were not allowed in the parent application. Claims 39-53 have been added and correspond to unallowed Claims 39, 41, 43, 44, 46, 47, 48, 50, 51, 54, 55, 57, 58, 61 and 62 in the parent application, respectively. Early and favorable action in connection with this application is respectfully requested.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: Sharon E. Crane  
Sharon E. Crane, Ph.D.  
Registration No. 36,113

P.O. Box 1404  
Alexandria, Virginia 22313-1404  
(703) 836-6620

Date: July 15, 2003